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98N-1265

Jeb Bush  
Governor

Robert G. Brooks, M.D.

2158 09 SEP 10 1999  
September 3, 1999

Elizabeth E. Hiner, RPh  
Assistant to the Director  
Division of Federal-State Relations, HFC 150  
Food and Drug Administration  
Rockville, MD 20857

Dear Ms. Hiner:

At its August 16-17, 1999 meeting in Tampa, the Florida Board of Pharmacy directed me to express its concerns regarding FDA's draft standard memorandum of understanding on compounded drug products. Of particular concern to the Board is the limit on interstate distribution. In our state it is not uncommon to have patients leave the state for extended periods of time. Any cap on the limit to interstate distribution would possibly pose undo hardship on patients who commonly make this annual migration to other states.

The Board would like to reaffirm its support for the memorandum of understanding that we sent to you last year (see copy), which does not limit interstate distribution. Or at a minimum, the Board would like you to consider relaxing the limit on interstate distribution of compounded products specified in the Administrations current draft memorandum of understanding. The Board considers the draft restrictions unnecessarily strict.

Thank you for your consideration of these comments. If you have any questions, or if I may be of any assistance, please let me know.

Sincerely,

John D. Taylor, RPh  
Executive Director  
Florida Board of Pharmacy

JDT/sk  
Enclosure: MOU (sent October 1998)

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**Proposed Memorandum of Understanding .**

**Between**

**The Florida Board of Pharmacy**

**And**

**The Food and Drug Administration**

**I. INTRODUCTION**

Pursuant to Section 127, "Pharmacy Compounding" of the Food and Drug Modernization Act of 1997, the Florida Board of Pharmacy has developed this memorandum of understanding to address specific issues related to compounded drugs. The purpose of this memorandum of understanding is to provide specific guidelines on the dispensing of compounded drug products.

**II. INVESTIGATION OF COMPLAINTS OF COMPOUNDED DRUGS SENT OUT-OF-STATE**

The board of pharmacy in the state in which the compounding pharmacy is located will investigate complaints about compounded drugs that are shipped out of state. That board may obtain the assistance of the board of pharmacy that is located in the state where the compounded drug was shipped.

**III. INORDINATE DISTRIBUTION OF COMPOUNDED DRUGS OUT-OF-STATE**

A pharmacy may dispense compounded drugs interstate, provided that the pharmacy notifies the state board of pharmacy with which it is registered and provides additional information that may be required by the board of pharmacy. The Florida Board of Pharmacy shall develop procedures to implement this notification requirement. This notification shall not be in lieu of any registration or licensure requirements that may be applicable to the pharmacy in the state into which it ships compounded medication.